GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:583
ANSWERED ON:27.07.2005
FINANCIAL SUPPORT FOR DEVELOPMENT OF AIDS VACCINE
Harsha Kumar Shri G.V.;Vallabbhaneni Shri Balashowry

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the testing of preventive HIV/AIDS vaccine is done on volunteers ;

(b) if so, the details of risks associated with said testing and precautions taken against the same ;

(c) whether the Government is extending financial support to the institutions which are in the process of developing AIDS vaccine ;

(d) if so, the details thereof;

(e) if not, the reasons therefor; and

(f) the details of results and side effects of the vaccine as tested on animals ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) & b) Yes Sir, Phase -1 trial of Adeno-Associated virus based vaccine has been initiated on 7th February 2005 at National AIDS Research Institute (NARI) Pune. Probable vaccine related risks are:-

i) Although it is unlikely but wild type AAV may cause complete vaccine replication.

ii) Volunteers may feel the sense of false security and indulge in risk behaviour.

iii) Local reaction like pain, swelling or redness can occur.

iv) Systemic reaction like mild fever, chills headache, nausea, vomiting may or may not occur. There is a possibility of unexpected side effect, although very unlikely to occur.

v) Vaccine cannot prevent HIV infection if volunteers become infected with HIV by any other mode of transmission.

In general vaccine appears to be well tolerated and no study product related serious adverse event has been noted so far. An independent international Safety Review Board [SRB] has reviewed the data and given go-ahead for enrollment for the mid-dose group.

The AAV vaccine, which is based on `C` clade has excellent safety profile with the dose used in Phase-I trial in Belgium and Germany. Only after the regulatory and social Committees in India have critically examined this data from other trial sites, the approval for Phase I trial was given.

The FDAs of Germany and Belgium have already cleared this vaccine for Phase I trial.

(c) to (e): No Sir, Government of India has signed a MOU with IAVI & ICMR for development of vaccine. This project is funded by International AIDS Vaccine Initiative (IAVI).

However, laboratory and the staff of the institute are being used.

(f) Studies have been conducted to determine potential toxicity, local tolerability in rabbits. Parameters of safety included morbidity and mortality, clinical observations, body heights, food consumption, ophthalmic examination., hematology, blood chemistry, urinalysis, gross necropsy, organ weight, histo-pathology and bio-distribution of vaccine DNA. There was no dose - dependent, clinically significant adverse events related to the test vaccine in any safety parameter and the vaccine was well tolerated at all dose levels and time points upto 180 days. The candidate vaccine was tested on other animals like mice and monkeys for safety and the animals did not show any significant adverse effects.

Scientific and regulatory bodies like NARI Scientific Advisory Committee, DCGI and Genetic Engineering Approval Committee (GEAC) have reviewed the results of toxicity /side effects of this vaccine on animals. Only after ascertaining that there are no probable

risk on human being associated with the vaccine, the phase I trial in normal healthy volunteers has been approved.